

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION**

UNITED STATES OF AMERICA

v.

CASE NO. 1:19cr00016

**INDIVIOR INC. (a/k/a Reckitt Benckiser
Pharmaceuticals Inc.) and
INDIVIOR PLC**

**MEMORANDUM IN SUPPORT OF DEFENDANTS’
MOTION FOR BILL OF PARTICULARS**

On April 9, 2019, a grand jury sitting in the Western District of Virginia returned a sprawling Indictment alleging that Indivior Inc. and Indivior PLC (collectively, “Indivior”) “executed an illicit nationwide scheme to increase prescriptions of Suboxone Film,” a product developed by Indivior for the treatment of opioid dependence. Indictment ¶ 1 (ECF No. 3). The Indictment alleges that “Indivior illegally obtained billions of dollars in revenue from Suboxone Film prescriptions by deceiving health care providers and health care benefit programs into believing that Suboxone Film is safer and less susceptible to diversion and abuse than other similar drugs.” *Id.* The Indictment also claims that Indivior “establish[ed] a telephone program for patients to call to be connected with a doctor for opioid addiction/dependence treatment, which Indivior used to connect patients to doctors Indivior knew were prescribing Suboxone and/or other opioids in a careless and clinically unwarranted manner.” *Id.* Based on these sweeping allegations, the Indictment charges both Indivior Inc. and Indivior PLC with one count of conspiracy to commit mail, wire, and health care fraud; one count of health care fraud; four counts of mail fraud; and twenty-two counts of wire fraud.

While the Indictment spans 47 pages and provides some detail regarding the charged offenses, the Indictment’s substance is lacking in other critical ways that, left unaddressed, raise

constitutional due process concerns. In particular, the Indictment fails to identify, much less address, every false or fraudulent statement or representation that the government may attempt to introduce at trial, lacks the factual basis to support the government's assertion that any statements and representations included in the Indictment are false or fraudulent, and fails to provide any details supporting the claim that Indivior somehow aided and abetted physicians in prescribing or dispensing Suboxone Film in a "clinically unwarranted manner." Moreover, the Indictment fails to identify Indivior's supposed co-conspirators, does not provide any information regarding a purported agreement underlying the alleged conspiracy, and fails to adequately identify the overt acts in furtherance of the conspiracy. The Indictment is further lacking in its identification of the locations in which certain alleged acts occurred, and it fails to specify any actions taken by Indivior PLC. For these reasons, addressed in further detail below, Indivior respectfully requests that the Court order the government to file a bill of particulars addressing these omissions so that Indivior may "adequately prepare a defense and avoid surprise at trial."¹ *See United States v. Sampson*, 448 F. Supp. 2d 692, 696 (E.D. Va. 2006) (quoting *United States v. Automated Med. Labs., Inc.*, 770 F.2d 399, 405 (4th Cir. 1985)).

LEGAL STANDARD

To provide a defendant with sufficient notice of the government's charges, an indictment must contain a "plain, concise, and definite written statement of the essential facts constituting the offense charged." Fed. R. Crim. P. 7(c)(1). In line with this standard, the indictment must include "all the essential elements of a criminal offense and sufficiently apprise the defendant of" the supporting facts so that "he will not be misled while preparing his defense" and so that he can

¹ Indivior has pending before the Court a Motion to Dismiss the Indictment with prejudice. (ECF No. 81). Should that motion be granted, this Motion for Bill of Particulars would be moot.

protect himself against a “later prosecution for the same offense.” *United States v. Hayes*, 775 F.2d 1279, 1282 (4th Cir. 1985). If the indictment lacks these necessary elements, the government remains free to shift its theory of prosecution up to and even during the trial, leaving the defendant to proceed to trial with key issues left undefined and vulnerable to unfair surprise. *See Russell v. United States*, 369 U.S. 749, 766 (1962).

Even if the basic standard in Rule 7(c)(1) is met, Rule 7(f) affords district courts broad discretion to order the government to file a bill of particulars if an indictment lacks the detail necessary to allow a defendant to prepare its defense. *See Fed. R. Crim. P. 7(f); United States v. Dulin*, 410 F.2d 363, 364 (4th Cir. 1969) (ordering a bill of particulars is within the “sound discretion” of the trial court); *see also United States v. Am. Waste Fibers Co.*, 809 F.2d 1044, 1047 (4th Cir. 1987) (A bill of particulars “serves to supply the evidentiary details needed to prepare a defense.”). Through a bill of particulars, a defendant can obtain information about “the nature of the charge against him so that he may prepare for trial, minimize the danger of surprise at trial, and . . . plead his acquittal or conviction in bar of another prosecution for the same offense.” *United States v. Schembari*, 484 F.2d 931, 934-35 (4th Cir. 1973). A bill of particulars thus “amplifies the indictment by providing missing or additional information so that the defendant can effectively prepare for trial.” *United States v. Fletcher*, 74 F.3d 49, 53 (4th Cir. 1996). Any doubt about the need for a bill of particulars “must be resolved in favor of disclosure and the conflicting concerns must yield to paramount public interest in affording the accused a reasonable foundation for mounting a defense.” *United States v. Manetti*, 323 F. Supp. 683, 696 (D. Del. 1971); *see also United States v. Thevis*, 474 F. Supp. 117, 124 (N.D. Ga. 1979)

(recognizing that the amendment to Rule 7(f) “requires that the defendant be given the benefit of the doubt in gray areas”), *aff’d*, 665 F.2d 616 (5th Cir. 1982).²

Courts routinely grant motions for bills of particulars in cases in which the “complexity and nature of the charges, and the extended period of time involved” would otherwise make it unfair to expect a defendant to prepare for trial without sufficient notice as to the details of the government’s charges. *See, e.g., United States v. Wharton*, No. ELH–13–0043, 2014 WL 1430387, at *12 (D. Md. Apr. 10, 2014), *aff’d*, 840 F.3d 163 (4th Cir. 2016). Particularly in cases alleging fraud, bills of particulars are necessary where indictments fail to identify “critical” information, including “the dates of the fraudulent conduct, the specific fraudulent documents, and the fraudulent statements within the documents.” *Sampson*, 448 F. Supp. 2d at 696; *see also United States v. Magalnik*, 160 F. Supp. 3d 909, 917 (W.D. Va. 2015); *United States v. Perry*, 30 F. Supp. 3d 514, 523 (E.D. Va. 2014); *United States v. Bortnovsky*, 820 F.2d 572, 574 (2d Cir. 1987) (defendants were “hindered in preparing their defense” when the government failed to “reveal crucial information” associated with fraud charges).

Voluminous discovery does not alleviate the need for a bill of particulars. *United States v. Locasio*, No. 4:05–476–RBH, 2006 WL 2796320, at *7 (D.S.C. Sept. 27, 2006). Rather, extensive discovery can make it more difficult for a defendant to identify the information it needs to adequately prepare a defense. *See United States v. Coleman*, No. 3:17-CR-00008, 2018 WL 1386265, at *5 (W.D. Va. Mar. 19, 2018) (“[T]he quantum of information provided may actually make it more difficult for Defendant to understand which parts of the last eight years of his life are actually at issue here.”); *Locasio*, 2006 WL 2796320, at *7 (“[T]he volume of

² While defendants were once required to show cause for the issuance of a bill of particulars, a 1966 amendment to Rule 7(f) eliminated that requirement to “encourage a more liberal attitude by the courts toward bills of particulars.” Fed. R. Crim. P. 7 advisory committee’s note to 1966 amendment.

discovery materials in a complex case may itself impede rather than assist the defense in its understanding of the government's case.” (quoting *United States v. Modi*, 197 F. Supp. 2d 525, 530 (W.D. Va. 2005))). Courts have thus ordered the government to provide defendants with additional specificity to support the charges in an indictment where extensive discovery has already been produced to the defendants in the case. *See, e.g., Coleman*, 2018 WL 1386265, at *5 (ordering a bill of particulars where the government provided “extensive discovery” to the defendant); *Magalnik*, 160 F. Supp. 3d at 917-18 (agreeing that the “enormous amount of discovery” would leave defendants to “sift through thousands of files . . . with limited ability to reasonably identify which documents the [g]overnment will attempt to prove false at trial”); *see also Bortnovsky*, 820 F.2d at 575 (“providing mountains of documents to defense counsel” when the indictment contained general allegations of fraud “impermissibly . . . shifted” the burden of proof to the defendants, necessitating a bill of particulars); *United States v. Bin Laden*, 92 F. Supp. 2d 225, 234 (S.D.N.Y. 2000) (“It is no solution to rely solely on the quantity of information disclosed by the government; sometimes, the large volume of material disclosed is precisely what necessitates a bill of particulars.”), *aff’d sub nom. In re Terrorist Bombings of U.S. Embassies in E. Africa*, 552 F.3d 93 (2d Cir. 2008).

ARGUMENT

I. The government must disclose each of the false or fraudulent statements it intends to introduce at trial and the factual basis for the alleged falsity or fraudulence.

The government's chief theory in this case appears to be that Indivior deceived health care providers and health care benefit programs into believing that Suboxone Film was safer, less divertible, and less abusable than other medication for opioid dependence. *See* Indictment ¶¶ 31-96. Yet the Indictment fails to identify all of Indivior's statements about Suboxone Film that it alleges were false, *see* Indictment ¶¶ 42 n.2, 90 n.4 (explaining that the statements listed were

merely “illustrative”), and otherwise lacks any explanation as to how the listed statements were actually untrue. Without more particulars detailing the statements that apparently form the basis for the government’s charges, and the factual basis for the alleged falsity or fraudulence of each one, Indivior does not have adequate notice of the charged offenses and will be unreasonably hindered in preparing its defense and subject to unfair surprise at trial.

“A defendant faced with false statements charges should not have to waste precious pre-trial preparation time guessing which statements he has to defend against . . . when the government knows precisely the statements on which it intends to rely and can easily provide the information.” *United States v. Trie*, 21 F. Supp. 2d 7, 21 (D.D.C. 1998). Accordingly, courts in this Circuit and elsewhere have held that bills of particulars are warranted when an indictment fails to delineate each fraudulent statement that the government seeks to introduce at trial and the basis for its alleged fraudulence. For example, in *United States v. Magalnik*, despite the fact that the indictment included tables identifying the date and content of alleged false statements and the government provided open file discovery, the district court ordered the government to file a bill of particulars listing “the specific visa and/or work applications that it intends to introduce at trial and explain[ing], in general terms, how each application is believed to be false or fraudulent.” 160 F. Supp. 3d at 918. Similarly, in *United States v. Anderson*, the court held that the defendant was “entitled to know precisely which allegedly false statements the government relies on in each paragraph, the way in which the government alleges them to be false, and when approximately they were allegedly made.” 441 F. Supp. 2d 15, 20 (D.D.C. 2006); *see also* *United States v. Elbaz*, 332 F. Supp. 3d 960, 982-83 (D. Md. 2018) (ordering government to list all allegedly false statements made by defendant “that it intends to introduce at trial, including the date of the statement and the person to whom it was made” because “the voluminous

discovery makes it difficult for the defense to identify” the statements that will be at issue); *Trie*, 21 F. Supp. 2d at 21-22 (“The government must provide information as to exactly what the false statements are, what about them is false, who made them, and how [the defendant] caused them to be made.”).

Here, although the government included tables in the Indictment with a series of purportedly “false and fraudulent statements and representations,” the Indictment also states that the allegations in the tables are only “illustrative examples,” rather than “an exhaustive list,” of the statements that allegedly provide the basis for the charges against Indivior. Indictment ¶¶ 42 n.2, 90 n.4. In addition, the Indictment alleges a conspiracy and fraudulent conduct that lasted from 2006 through the date of the Indictment in 2019, *id.* at ¶¶ 31-32, 78, but does not identify a single allegedly false or fraudulent statement or representation made after 2016. To the extent that there are other allegedly false or fraudulent statements the government intends to prove but has omitted from the Indictment, it should specify those statements in a bill of particulars to provide adequate notice and allow Indivior to prepare its defense.³ *See, e.g., United States v. Davidoff*, 845 F.2d 1151, 1154 (2d Cir. 1988) (reversing the defendants’ conviction and ruling that the district court abused its discretion by failing to require the government to state with particularity the unspecified violations referenced in the indictment through “includ[ing], but . . . not limited to” language).

³ To the extent the government identifies additional false or fraudulent statements or representations in a bill of particulars that are different from those alleged in the Indictment, Indivior reserves the right to challenge the government’s ability to introduce such statements at trial. *See, e.g., United States v. Floresca*, 38 F.3d 706, 712-14 (4th Cir. 1994) (en banc) (finding plain error where the district court failed to address the government’s constructive amendment of the indictment thereby “destroy[ing] the defendant’s substantial right to be tried only on charges presented in an indictment returned by a grand jury” (quoting *Stirone v. United States*, 361 U.S. 212, 217 (1960))).

Moreover, while the Indictment hinges on a theory that Indivior made false statements or representations that Suboxone Film was safer, less divertible, and less susceptible to pediatric exposure, the Indictment does not explain with any particularity how any of Indivior's statements on these issues were actually false. At most, the Indictment suggests that there was once a question as to whether Indivior's statements may have lacked substantiation. *See, e.g.*, Indictment ¶ 28 ("Suboxone Film's thin form *potentially* could make it easier to conceal, and thus more susceptible to smuggling than tablets; its individual packaging could make it more portable, including for reselling and sharing; and the serial numbers on the pouches were not electronically tracked and not shown to deter diversion." (emphasis added)); Indictment ¶ 29 ("INDIVIOR salespeople planned to raise 'diversion and misuse and pediatric safety' in sales presentations to physicians, even though there were no scientific studies to establish that Suboxone Film was safer with regard to diversion, misuse, or pediatric safety."). But the Indictment tellingly does not disclose the government's basis for charging that Suboxone Film was *not* safer, less susceptible to diversion, or less susceptible to pediatric exposure.

In fact, as the Indictment currently stands, it remains a mystery to Indivior how the government intends to prove the falsity or fraudulence of the relevant statements and representations, particularly in light of numerous statements by government agencies to the contrary. In 2012 and 2013, for example, the Food and Drug Administration ("FDA") expressly agreed with several of the statements now curiously listed in the Indictment without any explanation for assuming their falsity. After determining through statistical analysis that a switch to film packaging correlated with a drop in rates of pediatric exposure, Indivior (then known as Reckitt Benckiser Pharmaceuticals, Inc.) filed a Citizen Petition with the FDA in 2012, asking that the agency require all manufacturers of buprenorphine products to implement unit-

dose, child-resistant packaging as a matter of public safety to reduce the risk of child poisonings.⁴ Although the FDA denied the specific relief sought in Indivior's Citizen Petition, it agreed with many points raised by the company. All four of the FDA divisions and offices that considered the issue concluded that "Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging."⁵ Consistent with these conclusions, at an April 2013 meeting among generic buprenorphine manufacturers, the FDA informed the group that it viewed "the packaging of buprenorphine-containing products as a significant safety issue in regards to pediatric exposure," and recommended that each of the group's members voluntarily switch to unit-dose packaging for their buprenorphine-containing products.⁶

Dr. Daniel Budnitz, the Director of the Centers for Disease Control and Prevention's ("CDC") Medication Safety Program, has also recognized the impact of unit-dose packaging on pediatric exposure. In a CDC publication, Dr. Budnitz and others observed that a two-thirds drop in emergency department visits for pediatric ingestions of buprenorphine or naloxone followed an 80% increase in prescriptions dispensed in unit-dose packaging.⁷ This same

⁴ Citizen Petition from Tim Baxter, Glob. Medical Dir., Reckitt Benckiser Pharm., Inc. to Food & Drug Admin. 3 (Sept. 25, 2012) (RBP-00761351).

⁵ Citizen Petition Response from Food & Drug Admin. Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology (Feb. 14, 2012) (RBP0114_19147715); *see also* Citizen Petition Response from Division of Anesthesia, Analgesia, and Addiction Products (Dec. 6, 2012) (RBP0114_19147735); Citizen Petition Response from Division of Medication Error Prevention and Analysis (Feb. 14, 2013) (RBP0114_19147756-57); Citizen Petition Response from Division of Epidemiology (Feb. 14, 2013) (RBP0114_19147802).

⁶ Buprenorphine Prod. Mfrs. Grp. (BPMG), Meeting Minutes of FDA Call on BTOD REMS Submission 3-5 (Apr. 9, 2013) (RBP0114_19147639).

⁷ Daniel S. Budnitz, et al., Centers for Disease Control and Prevention, Notes from the Field: Pediatric Emergency Department Visits for Buprenorphine/Naloxone Ingestion—United States, 2008-2015, 65 Morbidity & Mortality Wkly. Rep. 1148 (2016).

publication explained that “[a] study of poison center calls for pediatric buprenorphine/naloxone exposures also found a significantly lower rate of calls involving film strips in unit-dose packaging, compared with tablets in multidose bottles.”⁸

In light of the nature of the charges in this case, the lack of any particularity in the Indictment addressing how Indivior’s similar statements are false or fraudulent, and the publicly available government statements suggesting otherwise, the government should be required to provide its factual basis in a bill of particulars for its allegation that each relevant statement or representation was false. This information is critical to Indivior’s understanding of the charges in the Indictment and its ability to prepare its defense. Without a bill of particulars specifying the statements the government alleges to be false and the facts indicating why the statements are deemed to be false, the government would be free to amend its Indictment improperly by changing its theories of prosecution, even during trial.

II. The government must detail the conduct supporting its allegation that Indivior devised a scheme to defraud by “marketing Suboxone Film to health care providers to be prescribed and dispensed in a careless and clinically unwarranted manner.”

In addition to alleging that Indivior made false and fraudulent statements and representations to health care providers and health care benefit programs, the Indictment claims that Indivior “market[ed] Suboxone Film to health care providers to be prescribed and dispensed in a careless and clinically unwarranted manner.” Indictment ¶ 31. This allegation suggests that Indivior somehow intentionally aided and abetted *careless* conduct on the part of physicians, and that the government believes such *careless* conduct by these physicians gives rise to federal criminal *fraud* charges, but the Indictment does not define what it deems to be “careless and clinically unwarranted” prescribing or dispensing, address how Indivior’s marketing aided

⁸ *Id.*

physicians in prescribing or dispensing Suboxone Film in a “careless and clinically unwarranted” manner, or link any false or fraudulent statements to the purported “careless and clinically unwarranted” prescribing practices. The critical link between Indivior’s purported support of certain providers and any instance of fraud using the mail or wires is entirely absent from the Indictment.

In addition, the Indictment alleges a list of “illustrative examples” of communications attributed to Indivior in furtherance of this ill-defined scheme, but not an “exhaustive list,” and nothing explaining how the “examples” provided constitute fraud by Indivior. *Id.* ¶ 102 n.5. In the first instance, the government must provide details regarding any action or communication it intends to prove at trial to support this claim.⁹ *See Davidoff*, 845 F.2d at 1154. But for all such actions or communications, the government must also state with particularity the details it believes support the allegation that Indivior’s marketing somehow caused certain physicians, each of whom were DEA registrants subject to monitoring and investigation, to prescribe and dispense Suboxone Film in a “careless and clinically unwarranted” manner. These details should include the identity of any relevant Indivior representatives, the identity of any relevant physicians or other health care providers, the details surrounding every instance in which the government believes Indivior’s marketing caused the relevant physicians to prescribe or dispense Suboxone Film in a “careless and clinically unwarranted manner,” the basis for concluding that the prescribing or dispensing was “careless and clinically unwarranted,” and the link between such conduct and the alleged fraudulent misstatement scheme. Without such critical

⁹ Here again, Indivior reserves its right to address any unlawful attempt to amend the Indictment once it becomes aware of any additional communications that the government intends to offer at trial. *See supra* n.3.

information, Indivior cannot even begin to understand the nature of the claim being asserted, and will thus be significantly hampered in the preparation of its defense.

III. The government must disclose the identity of Indivior’s alleged co-conspirators, summarize the agreement or agreements underlying its conspiracy charge, and identify the overt acts supporting the charge.

The Indictment further alleges that between 2006 and 2019, Indivior conspired with “others known and unknown to the Grand Jury” to commit mail fraud, wire fraud, and health care fraud. Indictment at p. 36. But not a single co-conspirator is identified. Moreover, the Indictment does not provide any other insight into Indivior’s purported co-conspirators, and it also fails to address any alleged agreement or agreements that form the basis for the conspiracy charge. In addition, rather than providing any detail on the overt acts in which Indivior and its co-conspirators are alleged to have engaged, the Indictment simply states that Indivior and its co-conspirators committed all the overt acts described in the Introduction and in the other twenty-seven Counts in the Indictment. Indictment at p. 37. Indivior cannot effectively prepare its defense and avoid unfair surprise at trial if it does not know the identity of its alleged co-conspirators or have insight into the purported agreement or acts forming the basis of the alleged conspiracy. *See United States v. Burgos*, 94 F.3d 849, 860 (4th Cir. 1996) (“[C]onspiracy is an inchoate offense, the essence of which is an agreement to commit an unlawful act.” (internal quotation marks omitted)).

In this Circuit and elsewhere, courts have ordered bills of particulars to address these specific issues. *See Coleman*, 2018 WL 1386265 at *5 (directing the government to disclose in a bill of particulars “the names of the co-conspirators the Government may use as witnesses” and “summariz[e] the agreement or agreements constituting the conspiracy charge”); *see also Am. Waste Fibers Co.*, 809 F.2d at 1047 (proper remedy for indictment that omits names of co-conspirators is to seek a bill of particulars); *United States v. Allen*, 289 F. Supp. 2d 230, 238

(N.D.N.Y. 2003) (directing government to disclose “the identities of all persons the government claims to have been co-conspirators during the course of the alleged conspiracy, regardless of whether they have been indicted”); *United States v. Lonzo*, 793 F. Supp. 57, 60 (N.D.N.Y. 1992) (similar); *United States v. Holman*, 490 F. Supp. 755, 762 (E.D. Pa. 1980) (similar). In particular, courts have held that the disclosure of co-conspirator names is warranted when the length of an alleged conspiracy and number of potential co-conspirators pose a risk of unfair surprise to defendants. *See United States v. Kahale*, 789 F. Supp. 2d 359, 372-74 (E.D.N.Y. 2009) (granting bill of particulars revealing the names of unindicted co-conspirators where the number of potential co-conspirators was large, the alleged conspiracy lasted five years, and the geographic scope was expansive). The identities of co-conspirators must also be provided when they are otherwise unidentifiable or when providing such information is in the interest of fundamental fairness. *United States v. Currie*, No. RDB 10–0532, 2011 WL 1527014, at *2 (D. Md. Apr. 20, 2011) (“In order to avoid unfair surprise at trial, and as a matter of fundamental fairness, Defendants have a right to know the names of their alleged co-conspirators.”).

Because the scope of a conspiratorial agreement is critical to understanding the nature of a charged conspiracy, courts have also ordered bills of particulars requiring the government to provide specifics regarding such an agreement. *See Coleman*, 2018 WL 1386265, at *5 (granting the defendant’s request for a bill of particulars to “summarize[e] the agreement or agreements constituting the conspiracy charge” in light of the potential that the defendant could otherwise be subject to surprise at trial or be unable to comprehend the charges against him); *United States v. Hsia*, 24 F. Supp. 2d 14, 32-33 (D.D.C. 1998) (ordering the government to produce a bill of particulars addressing “the scope of the alleged conspiratorial agreement” and whether and how “the acts of concealment alleged in the indictment were within the scope of the

conspiracy charged”). In ordering the government to provide the particulars of the alleged agreement or agreements forming the basis for a conspiracy charge, courts have required the government to indicate “when the agreement took place, with whom the agreement was made, and the nature of the agreement.” *United States v. Garibalde-Barron*, No. EP-12-CR-1406-KC, 2013 WL 427389, at *5 (W.D. Tex. Feb. 4, 2013); *see also Coleman*, 2018 WL 1386265, at *5 (requiring the government to identify in the bill of particulars “the approximate month and year of the alleged agreement” and “note the judicial districts where such agreements took place”).

Here, there are a number of factors that weigh in favor of a bill of particulars identifying all of Indivior’s purported co-conspirators. The conspiracy in this case is alleged to have lasted thirteen years, spanning numerous states. *See Kahale*, 789 F. Supp. 2d at 372 (ordering a bill of particulars identifying the identity of all unindicted co-conspirators where, among other things, the conspiracy was alleged to have lasted for five years and spanned a number of locations). Although the number of purported co-conspirators is nowhere hinted at, the Indictment vaguely suggests the number may be substantial; the Indictment merely states that Indivior conspired with “others” who remain unindicted, unnamed, and potentially unknown. *See id.* (identifying the universe of potential co-conspirators as “potentially large”). There is also no basis in this case to fear that revealing the identities of the unindicted co-conspirators will jeopardize their safety, create risk of witness tampering, or compromise an ongoing government investigation. *See id.* at 373 (explaining the lack of “any legitimate basis for concern about” the disclosure of the co-conspirator identities “in this white-collar fraud action involving no allegations of violence”). And the relative complexity of the fraud charges Indivior is facing in this case weighs in favor of disclosure given that such charges carry a greater potential for causing unfair

surprise. *Id.* (“Certain charges, such as the fraud charges alleged here, by their nature carry a greater potential for causing unfair surprise at trial due to their complexity.”).

Moreover, the Indictment’s failure to identify all of the fraudulent conduct the government seeks to prove at trial provides a further basis for requiring the disclosure of Indivior’s purported co-conspirators. As noted above, the Indictment does not identify a single fact after 2016, three years before the alleged end of the purported thirteen-year conspiracy. Thus, an interest in “fundamental fairness” dictates that the government must provide such information to Indivior. *Currie*, 2011 WL 1527014 at *2 (ordering a bill of particulars to identify the names of alleged co-conspirators where the defendants left their relevant positions between 18 to 24 months prior to the alleged end date of the conspiracy).

The Indictment also fails to allege any agreement among these purported co-conspirators let alone specify any facts surrounding an agreement. Without any such information, Indivior has no basis for determining whether any particular alleged act can properly be regarded as having been performed in furtherance of the alleged conspiracy. Moreover, instead of pointing to specific overt acts supporting the conspiracy charge, the Indictment simply refers to all the acts that are alleged in connection with the twenty-seven other Counts, which does not provide Indivior with any notice as to the nature of the conspiracy charged. To allow Indivior to prepare for trial and prevent undue surprise, the Court should thus order the government to summarize the nature of the agreement or agreements underlying the conspiracy charge, indicate when and where the agreement took place and between whom the agreement was made, and specify the overt acts that are alleged to have been committed in furtherance of the conspiracy. *See Coleman*, 2018 WL 1386265, at *5; *Garibalde-Barron*, 2013 WL 427389 at *5; *Hsia*, 24 F. Supp. 2d at 32-33.

IV. The government must specify the location information surrounding the alleged referrals to Doctor A.

In connection with its apparent claim that Indivior somehow aided physicians in prescribing Suboxone Film in an undefined “careless and clinically unwarranted manner” (see Section II above), the Indictment alleges that Indivior used a telephone referral program, known as “Here to Help,” to “connect patients to doctors Indivior knew were prescribing Suboxone and/or other opioids” in such a manner. Indictment ¶¶ 1, 102. On the basis of this purported scheme, the Indictment charges eighteen counts of wire fraud based on alleged referrals to “Doctor A,” but fails to identify the specific locations from which each referral call originated, the locations of the Here to Help call centers where each referral call was answered, and the locations of the doctor’s offices to which the referral was actually made. *See* Indictment at p. 42.

“There is a long history of courts directing the government to provide a bill of particulars where the location of the alleged criminal conduct is unclear in the indictment.” *See, e.g., United States v. Jones*, No. 7:16-cf-30026, 2017 WL 1169754, at *2 (W.D. Va. Mar. 27, 2017) (collecting cases); *Holman*, 490 F. Supp. at 762 (ordering the government to disclose “the exact date and place, if known . . . , of each event alleged in the indictment for which such information has not yet been given”). Here, the location of the alleged criminal conduct supporting these wire fraud charges is unclear, and it is necessary to Indivior’s preparation of its defense. The location information should therefore be provided in a bill of particulars to allow Indivior to sufficiently prepare for trial.

V. The government must identify any actions attributable to Indivior PLC.

Finally, the government must specifically identify any fraudulent statements or representations purportedly made or any alleged actions taken by Indivior PLC, the British public company that owns Indivior Inc. According to the Indictment, both Indivior Inc. and

Indivior PLC conspired with others to and committed health care, mail, and wire fraud.

Indictment at p. 36-42. Yet the Indictment is devoid of any particularized allegations regarding Indivior PLC's conduct or statements that would allow it to prepare a defense.

The Indictment refers to Indivior, Inc. as simply "INDIVIOR" and refers to Indivior PLC as "INDIVIOR PLC." *Id.* at ¶¶ 2-3. While the Indictment generally alleges that Indivior PLC was involved in the alleged schemes, it only lists actions taken by "INDIVIOR" as the basis for those schemes. For example, the Indictment claims that "INDIVIOR" sought the FDA's agreement that Suboxone Film's packaging would protect against diversion and child exposure, *id.* at ¶ 24, "INDIVIOR" executives and sales representatives made allegedly false representations to health care providers and health care benefit programs, *id.* at ¶¶ 42-72, 91-96, and "INDIVIOR" allegedly used the Here to Help telephone program to refer patients to physicians that it knew prescribed opioids in a careless and clinically unwarranted manner, *id.* at ¶¶ 102-143.

Given that the Indictment generally asserts that Indivior PLC was involved in the alleged fraud scheme, it is crucial that the Court order a bill of particulars requiring the government to specify—as to Indivior PLC—"the dates of the fraudulent conduct, the specific fraudulent documents, and the fraudulent statements within the documents." *Sampson*, 448 F. Supp. 2d at 696. Without such information, Indivior PLC will undoubtedly be subject to unfair surprise at trial and unable to adequately prepare a defense. When it comes to understanding its purported role in the alleged fraud scheme, the conclusory allegations in the Indictment do nothing to provide Indivior PLC with the information it needs. *See Perry*, 30 F. Supp. 3d at 523 (explaining that "in cases involving vaguely asserted charges of fraud, . . . a bill of particulars may be necessary in order to provide a defendant a full and fair opportunity to prepare a defense").

VI. The voluminous discovery produced by the government does not cure the gaps in the Indictment.

“Perhaps the most frequent case in which particulars are warranted is where discovery is overwhelmingly extensive and the government fails to designate which documents it intends to introduce and which documents are merely relevant to the defense.” *United States v. Mahaffy*, 446 F. Supp. 2d 115, 119 (E.D.N.Y. 2006) (emphasis omitted). That makes sense, of course, since defendants should not have to spend months combing through millions of pages of documents—or hundreds of thousands of hours of audio and video recordings—to understand the charges against them. *See, e.g., United States v. Ramirez*, 609 F.3d 495, 503 (2d Cir. 2010) (noting that the “district court made clear that it ordered a bill of particulars because so much discovery was produced to the defendants, not too little”); *Trie*, 21 F. Supp. 2d at 21 n.12 (“The open file discovery, amounting to making available . . . approximately 1.9 million documents, is no substitute for adequate specification of the crimes with which [the defendant] is charged.”); *Magalnik*, 160 F. Supp. 3d at 917 (requiring bill of particulars in a case where the government produced “135,422 rows of Excel data, 13,929 pages of documents, 79 photographs, and 4 audio CDs”).

To date, the government has not provided the constitutionally required specificity that is necessary for Indivior to navigate the more than 8 terabytes worth of data produced in this case and identify the requested information in a reasonable manner. Without such specificity from the government, Indivior cannot be expected to bear the burden of filling the gaps in the Indictment to identify (1) every false or fraudulent statement the government intends to introduce at trial, (2) the reason why the government contends those statements are false or fraudulent, (3) the details surrounding the claim that Indivior’s marketing aided and abetted physicians in prescribing and dispensing in “a careless and clinically unwarranted manner,” (4) the identity of

Indivior's purported co-conspirators, (5) the nature of the agreement or agreements supporting the purported conspiracy charge, (6) the specific overt acts allegedly committed in furtherance of the conspiracy, (7) the locations to and from which each Here to Help referral call was made, and (8) the actions attributable to Indivior PLC. This is a complex case with an Indictment lacking in the specificity necessary to permit Indivior to prepare its defense and to prevent unfair surprise at trial. The government should thus be required to produce a bill of particulars.

CONCLUSION

For the foregoing reasons, Indivior respectfully requests that the Court enter an order requiring the government to produce a bill of particulars providing separately and specifically for each of Indivior Inc. and Indivior PLC, the following information:

1. Every false or fraudulent statement or representation the government intends to introduce at trial;
2. The factual basis for the government's assertion that any such statement or representation is false or fraudulent;
3. Every action or communication supporting the claim that Indivior's marketing aided or abetted physicians in prescribing or dispensing Suboxone Film in a "careless and clinically unwarranted manner," including:
 - a. The identity of any relevant Indivior representatives;
 - b. The identity of any relevant physicians or other health care providers;
 - c. The details surrounding the alleged actions or communications that purportedly caused the relevant physicians to prescribe or dispense Suboxone Film in a "careless and clinically unwarranted manner";

- d. The basis for concluding that the prescribing or dispensing was “careless and clinically unwarranted”; and
 - e. The link between any false or fraudulent statements to the purported “careless and clinically unwarranted” prescribing practices;
- 4. The identity of all co-conspirators;
- 5. The nature of any agreement or agreements supporting the asserted conspiracy charge, including:
 - a. When the agreement took place (approximate month and year);
 - b. Where the agreement took place (the relevant judicial district); and
 - c. The identity of the individuals or entities entering into the agreement;
- 6. The specific overt acts committed in furtherance of the alleged conspiracy;
- 7. The locations to and from which each Here to Help call was made that allegedly resulted in a referral to Doctor A, including:
 - a. The specific location from which each referral call originated;
 - b. The location of the Here to Help call center where each referral call was answered; and
 - c. The location of the doctor’s office to which each referral was made;
- 8. Any actions attributable to Indivior PLC, including:
 - a. The dates of any purported fraudulent conduct;
 - b. The identity of any specific fraudulent documents reflecting action by Indivior PLC;
 - c. Any fraudulent statements attributable to Indivior PLC; and

- d. The factual basis for the government's assertion that any such statement or representation is false or fraudulent.

Dated: September 10, 2019

Respectfully submitted,

INDIVIOR INC. (a/k/a Reckitt Benckiser
Pharmaceuticals Inc.) and INDIVIOR PLC

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By Counsel

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CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing to be presented to the Clerk of the Court for filing and uploading to the CM/ECF system, which will send notification of such filing to all counsel of record, on this 10th day of September, 2019.

/s/ Thomas J. Bondurant, Jr. _____

Counsel for Defendants